AMENDMENTS TO THE CLAIMS

1. (Currently amended) [[-]] **A process** for the preparation of anhydrous active pharmaceutical ingredients (API's), which are taxane derivatives, solubilizing a hydrated taxane derivative in a solvent that is chemically inert and forms an azeotrope with water, removing the water of hydration by azeotropic distillation at a temperature between -20 and 200°C and at a pressure between <0.001 and 780 mm Hg, resulting in the anhydrous compound with an amount of water less than 1.0% w/w.

2. (Currently amended) **The process** according to claim 1 in which anhydrous (2R,3S) 4-acetoxy-2-α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13α-il 3-tert butoxycarbonylamino-2-hydroxy-3-phenylpropionate (I) is obtained as a product.

3. (Canceled)

4. (Currently amended) **The process** according to claim 2, in which the solvent used in step a) is a mixture of solvents.

5. (Currently amended) **The process** according to claim 4 in which the solvent employed is an alcohol, an organic acid, a halogenated solvent, an aromatic solvent or other solvent, of sufficient polarity, to effect the solubilization of the hydrated product.

6. (Currently amended) **The process** according to claim 5 in which the solvent employed is a linear or branched chain alcohol.

7. (Currently amended) **The process** according to claim 3 in which in steps a) and b) the (2R,3S) 4-acetoxy-2-αbenzoyloxy-5β-20-epoxy-l,7-β-10-R-tri-hydroxy-9-oxo-tax-ll-en-13α-il 3-tert-butoxycarbonylamino-2-hydroxy-3- phenylpropionate (I) is hydrated with between 1 to 20% water and the solvents employed are absolute ethanol and toluene in a relative proportion close to 1:9, at a temperature between 10 and 70°C and at a pressure between 10 and 100 mm Hg.

8. (Currently amended) **A process** for the preparation of anhydrous (2R,3S)4acetoxy-2-α-benzoyloxy-5β-20-epoxy-l,7-β-10-β-tri-hydroxy-9oxo-tax-ll-en-13α-il 3-tert-butoxycarbonylamino-2-hydroxy-3phenylpropionate (I) reacting di-tertbutyl-dicarbonate (>99% purity) and N-desacetyl-N-debenzoyl paclitaxel (>98% purity), in equimolar quantities, employing an anhydrous solvent, and directly isolating in a pure and anhydrous form, (2R,3S) 4-acetoxy-2-α-benzoyloxy-5β-20-epoxy-l,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13a-il 3-tertbutoxycarbonylamino-2-hydroxy-3-phenylpropionate (I).

9. (Currently amended) The process according to claim 8 in which the anhydrous solvent employed is an aliphatic or cyclic ether.

10. (Currently amended) The process according to claim 9 the solvent employed is anhydrous tetrahydrofuran.

11. (Currently amended) A process for the preparation of anhydrous (2R,3S)4-acetoxy-2-α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9oxo-tax-ll-en-13α-il 3-tert-butoxycarbonylamino-2-hydroxy-3phenylpropionate (I) comprising purifying impure (2R,3S)4-acetoxy-2-α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-ll-en-13α-il 3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate (I) by chromatography.

12. (Currently amended) The process according to claim 11 in which the chromatographic technique employed is normal or reverse phase.

13. (Currently amended) The process according to claim 11 the chromatography is conducted using gradient elution with a solvent or a mixture of solvents.

14. (Currently amended) The **process** according to claim 11 in which a mixture of alkane and ester solvents is used, and that the stationary phase employed is either SiO2 or Al_2O_3.

15. (Currently amended) The **process** according to claim 14 in which the mixture of solvents used consists of ethyl acetate and hexane in a proportion close to 20:80, changing gradually to a proportion of 80:20 and the stationary phase employed is either SiO_2 or Al_2O_3.

16. (Currently amended) The **process** according to claim 12 or 13 in which the mixture of solvents employed is a mixture of methanol or acetonitrile and water or an aqueous buffer solution in the proportion close to 85:15, gradually changing to a proportion close to 75:25 and the stationary phase employed is a chemically modified silica gel.

17. (Currently amended) **A process** for the preparation of the stable hydrates of (2R,3S) 4-acetoxy-2-α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13α-il 3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate (III), comprising solubilizing (2R,3S) 4-acetoxy-2-α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13α-il 3-tert-butoxycarbonylamino-2hydroxy-3-phenylpropionate (I) in a solvent selected

from the group consisting of a polar aprotic solvent, a cyclic ether and a polyethoxylated sorbitol and mixing the solution thus obtained with water or a mixture of water and a co-solvent, to induce crystallization, and isolating, washing and drying the crystals of (2R,3S) 4-acetoxy-2α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13α-il 3-tert-butoxycarbonylamino-2-hydroxy-3-

phenylpropionate · 3 H_2O (III).

18. (Currently amended) **The process,** according to claim 17 in which the polar aprotic solvent employed is selected from the group consisting of N,N-dimethylformamide, N,N-dimethylacetamide and

dimethyl sulfoxide, the cyclic ether is dioxane or tetrahydrofuran, and the polyethoxylated sorbitol employed is polysorbate 80.

19. (Currently amended) **The process,** according to claim 17 in which the solvent employed to solubilize the (2R,3S) 4-acetoxy-2-α-benzoyloxy- 5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13α-il 3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate (I) is capable of solubilizing, or is miscible with, between 3 and 200,000 molar equivalents of water.

20. (Currently amended) **The process,** according to claim 17 in which the solvent used to solubilize the (2R,3S) 4acetoxy-2-α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13α-il 3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate (I) is polysorbate 80 and the water for inducing crystalization is mixed with an alcohol containing between 1 and 8 carbons as a co-solvent.

21. (Currently amended) **The process,** according to claim 20 in which the solvent employed is polysorbate 80, and the water for inducing crystallization is mixed with ethanol as a co-solvent.

22. (Currently amended) **The process,** according to claim 20 in which the solvent employed is polysorbate 80, and the water for crystalization is mixed with n-butanol as a co-solvent.

23. (Currently amended) **The process,** according to claim 17 characterized by the fact that the quantity of water employed is approximately 2,000 molar equivalents relative to the

quantity of the (2R,3S) 4-acetoxy-2-α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13α-il 3 tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate (I).

24. (Currently amended) The process, according to claim 23 in which the quantity of alcohol employed as a co-solvent is approximately 60 molar equivalents relative to the quantity of the (2R,3S) 4-acetoxy-2-α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13α-il 3-tertbutoxycarbonylamino-2-hydroxy-3-phenylpropionate (I).

25. (Currently amended) The process, according to any one of claims 17 to 24 in which the final concentration of the (2R,3S) 4-acetoxy-2-α-benzoyloxy-50-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13α-il 3-tertbutoxycarbonylamino-2-hydroxy-3-phenylpropionate (I), in polysorbate 80 is in the range of 0.025 to 0.067 mg/mL, before admixture with water or water and co-solvent.

26. (Currently amended) The process, according to claim 17 in which the product (III) obtained is dried over a dessicant at ambient temperature.

27. (Currently amended) **A process,** according to claim 17 in which the product (III) obtained is dried over P_2O_5 at ambient temperature.

28. (Currently amended) **A process,** for the preparation of concentrated, sterile solutions of active pharmaceutical ingredients (API's), which are taxane derivatives, comprising adding to said API a solvent or mixture of solvents of sufficient polarity to effect complete solubilization of the active principle, said solvent being selected from the group consisting of water, ethanol, polyethoxylated sorbitol, lecithin, vegetable oils, and mixtures thereof, and adding a stabilizing agent such as an acid and/or antioxidant, to obtain a solution stable for greater than or equal to 24 months when stored under an inert atmosphere at between 2 and 8°C.

29. (Currently amended) **The process,** according to claim 28 in which the API is anhydrous (2R,3S) 4acetoxy-2-α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13α-il 3-tert-butoxycarbonylamino-2-hydroxy-3phenylpropionate (I).

30. (Currently amended) **The process,** according to claim 28 in which the API is (2R,3S) 4-acetoxy-2-α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13α-il 3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate · 3 H_2O (III).

31. (Currently amended) **The process,** according to claim 28 in which the API is 4-acetoxy-2-α-benzoyloxy-5-αβ-20-epoxy-1,7-β-10-β-tri-hidroxy-9-oxo-tax-11-25-en-13α-il (2R,3S) 3-benzoylamino-2-hydroxy-3-phenylpropionate (II).

32. (Currently amended) **The process,** according to claim 28 a polyethoxylated sorbitol is employed as the vehicle.

33. (Currently amended) **The process,** according to claim 32 in which the API is either anhydrous (2R,3S) 4acetoxy-2-α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13α-il 3-tert-butoxycarbonylamino-2-hydroxy-phenylpropionate (I), (2R,3S) 4-acetoxy-2-α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13α-il 3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate · 3 H_2O (III), or 4-acetoxy-2-α-benzoyloxy-5-β-20-epoxy-1,7β-10-β-tri-hidroxy-9-oxo-tax-11-en-13a-il (2R,3S) 3-benzoylamino-2-hydroxy-3-phenylpropionate (II) and the API is slowly added with

agitation under an inert atmosphere to the vehicle, to which has been previously added a stabilizing agent, until complete solubilization of the API is achieved; and the solution thus obtained is filtered through a sterilizing membrane having a porosity less than or equal to 0.45 μm.

34 – 39. (Canceled)

40. (Currently amended) **The process,** according to claim 28 or 37 whereby the solvent employed is polysorbate 80 and the stabilizing agent is either acetic or ascorbic acid, or a combination thereof, added in sufficient quantity such that the pH of the resulting solution is between 3.5 to 4.5.

41. (Currently amended) **An article of manufacture comprising a pharmaceutical composition** comprising one or more anhydrous or hydrated taxane derivatives, which is sterile and is stable for greater than or equal to 24 months when stored under an inert atmosphere at between 2 and 8°C and filled in sterile, pyrogen free recipients for single or multiple use.

42. – 44. (canceled)

45. (New) **The process,** according to claim 33, in which the stabilizing agent is an organic or inorganic acid selected from the group consisting of aspartic acid, acetic acid, citric

acid, ascorbic acid, phosphoric acid, pyrophosphoric acid, hypophosphoric acid, hydrochloric acid, sulfuric acid, propionic acid, sorbic acid, erythorbic acid, caprylic acid, gallic acid, gluconic acid, benzoic acid, thiodipropionic acid, sulfurous (H2SO3) acid, a saturated fatty acid and an unsaturated fatty acid.

46. (New) **The process** according to claim 45 in which a combination of two or more stabilizing agents is employed.

47. (New) **The process,** according to claim 24 or 33 in which the solvent employed is polysorbate 80 and the stabilizing agent is acetic acid, citric acid, ascorbic acid, or a combination thereof, added in sufficient quantity such that the pH of the resulting solution is between 3.5 to 4.5.

48. (New) A pharmaceutical composition comprising anhydrous (2R,3S) 4acetoxy-2-α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13α-il 3-tert-butoxycarbonylamino-2-hydroxy-phenylpropionate (I), (2R,3S) 4- acetoxy-2-α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13α-il 3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate ·3 H_2O (III), or 4-acetoxy-2-α-benzoyloxy-5-β-20-epoxy-1,7β-10-β-tri-hidroxy-9-oxo-tax-11-en-13a-il (2R,3S) 3-benzoylamino-2-hydroxy-3-phenylpropionate (II) and one or more polyethoxylated sorbitol(s).

49. (New) A method for treating a neoplastic tumor that is responsive to treatment with an agent that inhibits the depolymerization of tubulin comprising administering to a subject in need thereof an effective amount of the pharmaceutical composition of claim 48.